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| EXAMINER | |
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| PAK, JOHN D | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/600,006 | ARATA, ANDREW B. | |
| | Examiner | Art Unit | |
| | John Pak | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *30 and 36-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30 and 36-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 30 and 36-46 are pending in this application.

At the outset, the following claim interpretation is noted:

Claim 36: Complex of the formula $Ag^{+}CA^{-}$ wherein the concentration is claimed in terms of % by volume

$Ag^{+}CA^{-}$ is *not* a liquid at ambient temperature.

Therefore, the only "volume" it has is the volume it takes up within the solvent. Since the solvent is water + citric acid, this feature can be interpreted, in the absence of contrary evidence, as that volume which $Ag^{+}CA^{-}$ takes up within the solvent.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no originally filed disclosure that provides adequate descriptive support for the **$Ag^{+}CA^{-}$ complex having the now-specified percent by weight or ppm** as fully set forth in the instant rejected claims. The following was originally disclosed regarding the $Ag^{+}CA^{-}$ complex (specification pages 21-22) (emphases added):

Nuclear magnetic resonance tests (1H NMR) were preformed on the silver citrate formed in accordance with the above process and a blank citric acid sample. The samples showed an overwhelming excess of citric acid, with little or no other anions present. It is postulated the Ag must be in the form of the cation Ag+ complexed with the citric acid. It is theorized the empty 5s orbital of Ag+ overlaps with the delocalized π bond on one of the carboxyl groups of citric acid. The citric acid anion is the counterion for this complex ion (Ag(CA)x)+ I.e. (CA). CA is citric acid or is ($C_6H_8O_7 \cdot H_2O$). Another possibility is a zwitterion, where the negative charge is on the complex itself, (Ag+CA-) where the total charge of the complex is neutral. Either or both of these species may exist in the silver citrate formed in accordance with the above process. Multiple complexation to Ag+ is also possible.

Therefore, applicant's original specification disclosed uncertainty ("postulated") as to which complex(es) is/are truly obtained and present in the inventive composition. Given that several different complexes ("either or both," "multiple complexation") may be present in applicant's solution, it is new matter to claim that all the weight percentages or ppm is now attributable only to the $Ag^+CA^-$ complex. That is to say, the weight percentage features of claims 41-46 lack adequate descriptive support from the originally filed disclosure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al.

Srivastava et al. explicitly disclose a 0.5% aqueous solution of silver citrate in water (page 209, right column). Table I discloses antibacterial activity (page 211).

Independent claim 30 recites an aqueous solution comprising citric acid and the $Ag^{+}CA^{-}$ complex. Applicant asserts that the $Ag^{+}CA^{-}$ complex is different from conventional silver citrate because it is much more soluble (specification page 21, lines 14-17). Here, the cited prior art shows a much more soluble silver citrate. $Ag^{+}CA^{-}$ complex is presumed and the burden is shifted back to applicant to show otherwise.

In this regard, the 132 declaration filed by Pullman is noted (filed 3/27/2007). The Examiner cannot agree with Mr. Pullman's declaration statements or conclusions for the following reasons.

The fundamental flaw in the declaration is the premise that there must be something wrong with Srivastava's article because trisilver citrate cannot be soluble to 0.5% in water. Declaration Exhibit F is a Merck Index entry for silver citrate from 1968. Declarant admits, "Exhibit F ... which is a widely acknowledged as an important scientific reference of chemical compounds, is from the same period of time as

Srivastava's article" (declaration paragraph 10). So, looking more closely into Exhibit F, the following is noted:

> **Silver Citrate.** Itrol; Silberol. $C_6H_8Ag_3O_7$; mol wt 512.74. Anhydr citric acid 37.47%, C 14.05%, H 0.98%, Ag 63.12%, O 21.84%.
> White, odorless, heavy, cryst powder; darkens in light. Soluble in 3500 parts water, more soluble in boiling water; readily soluble in dil $HNO_3$, ammonia. *Protect from light.*
> MED USE: Has been used as antiseptic dusting powder for wounds.

At least since 1968, the skilled artisan in this field would have known that silver citrate is "readily soluble" in dilute nitric acid and ammonia. Hence the pH of the aqueous environment would have been clearly recognized as substantially influencing solubility.

Thus, in reading Srivastava's 0.5% silver citrate aqueous solution disclosure, published in 1970, one skilled in the art would have recognized that the additional solubility is completely acceptable, and not something that must be dismissed as factual error or typographical error, as the declaration alleges.

Further, additional solubility is indicative of some change in how the silver reacts to its aqueous environment. Therefore, the Examiner has established sufficient basis for shifting the burden back to applicant in establishing that Srivastava's 0.5% aqueous solution of citric acid does not in fact contain a complex of the formula $Ag^+CA^-$.

In this regard, the Examiner notes the declaration comparison of $Ag_3CA$ and Axenohl™. The flaw in this experimental design is that the declaration continues to

disregard the 0.5% silver citrate concentration that is explicitly disclosed by Srivastava et al. 0.5% silver citrate in an acidic solution (as known in the art from "widely acknowledged as an important scientific reference") should have been tested since that is how one skilled in the art would know to obtain 0.5%. The declaration instead tests 0.04 g of silver citrate in 100 g of deionized water (0.04% by weight). The experiment was thus set up to fail: trisilver citrate solution was made and tested, so what else could result.

The declaration also criticizes the Srivastava article in another respect. The declaration states that the following sentence from the abstract shows Srivastava et al. could not have disclosed or had the silver citrate of the present invention: "Surgical gauze treated with silver citrate showed good bacteriostatic activity but had not bactericidal activity." The declaration makes the argument that lack of bactericidal activity strongly suggests that Srivastava's silver citrate solution was not actually 0.5% in concentration. The Examiner cannot agree. The bactericidal activity protocol is provided by Srivastava et al. on page 210, right column. This is a rather unique protocol and specific to that particular experimental design for surgical gauzes. Such experiment does not provide any indication as to whether a 0.5% silver citrate solution not in a gauze would provide or not provide bactericidal activity in a different challenge test. Such indirect argument fails to overcome the explicit disclosure of 0.5% silver citrate

aqueous solution. That is what was disclosed, so that is what applicant must show as being different, not some erroneously presumed lower concentration of silver.

It is noted that claims 30 and 36-40 require citric acid, some claims at concentrations of unspecified percentages. As discussed at the outset of this Office action, the percentages without specific basis therefor can be broadly interpreted to lack any limiting function. For example, "10% citric acid" could mean 10 wt% citric acid or 10% of a citric acid that is extremely dilute, which results or read on negligible or equilibrium amount of citric acid.

Relatedly, it is noted that citric acid's $pKa_1$ is 3.13, $pKa_2$ is 4.78, and $pKa_3$ is 6.43 (Dictionary of Organic Compounds, Vol. 2, page 1552, first column). This degree of difference in pKa's (i.e. not too large) means that acidic content of a citric acid solution has substantial contribution from all three protons. However, if the predominant species in the aqueous solution of citric acid were dihydrogen citrate (mono-deprotonated citric acid), silver ions would react to make silver dihydrogen citrate, $Ag^+CA^-$. Thus, it would have been reasonable to the skilled artisan to understand that the more acidic the solution that contains citric acid is, the more protonated species would predominate, and more likely it is that the mono-deprotonated $CA^-$ species (dihydrogen citrate) would be present in higher concentration. Again, such consideration further supports the shifting of the burden back to applicant to show that the 0.5% silver citrate explicitly disclosed by Srivastava et al. does not contain $Ag^+CA^-$, as applicant asserts.

Applicant's arguments relative hereto, filed on 12/26/2007, have been given due consideration, but they were deemed unpersuasive.

Applicant argues that "Srivastava fails to disclose the presence of nitric acid and/or ammonia in the silver citrate solution that could facilitate the reported solubility values." Applicant takes this line of argument further by stating that nitric acid and/or ammonia can potentially injure any tissue that comes in contact with it, so consideration of skin sensitization would not have included such ingredients.

Applicant's argument is too narrow and ignores the skill of the ordinary skilled artisan. The Merck Index disclosure from 1968 showed that even though silver citrate has limited solubility in water, it becomes "readily soluble" in dilute $HNO_3$ and ammonia. Applicant blindly interprets this to mean that only nitric acid and ammonia would be understood to make silver citrate more soluble. Hardly, the disclosure would have been understood by the ordinary skilled artisan that pH of the aqueous environment would have substantial influence on solubility. Therefore, absence of nitric acid or ammonia does not militate against Srivastava's explicit disclosure of 0.5% aqueous solution of silver citrate. From the substantially more soluble silver citrate, i.e. 0.5% silver citrate, $Ag^{+}CA^{-}$ complex is presumed for the reasons of record.

For these reasons, all claimed features are met and the claims are anticipated.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30 and 36-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,197,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the full reasons set forth on page 7 of the Office action of 8/12/2005. The patented claims disclose the $Ag^{+}CA^{-}$ complex (claim 7), citric acid has a concentration of greater than 1.0% by volume (claims 4-5), and the silver citrate has a concentration of ≥ 5 ppm silver (claim 5). One having ordinary skill in the

art would have therefore recognized the instant invention as an obvious variation of the claimed invention in the cited patent.

Claims 30 and 36-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 9, 18-19 and 30-32 of copending Application No. 10/936,465. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims recite or read on a composition that contains silver dihydrogen citrate + water + citric acid. The citric acid can be present in an amount greater than 5% or greater than 10% (claims 30-32).

Even though the specific concentration of the silver dihydrogen citrate claimed in the instant application is not expressly claimed in the copending application claims, such range of concentration given the well known silver antimicrobial activity would have been within the skill of the ordinary skilled artisan. Therefore, the ordinary skilled artisan in this field would have recognized that the instant invention is an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30 and 36-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 9, 18-19 and 30-32 of copending Application No. 11/144,398. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the same reasons as those set forth above for 10/936,465. The affected claims of the two copending applications are substantially the same, so the same reasons apply. Therefore, the ordinary skilled artisan in this field would have recognized that the instant invention is an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 30 and 36-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/729,175. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 1 of the copending application is directed to a composition comprising anhydrous silver dihydrogen citrate and citric acid. First, this composition is open to an aqueous solution thereof. Second, water could be added from the motivation to more easily apply the silver active ingredient, and the result would be the subject matter of the instant application, wherein the various aqueous concentration percentages would have

been obtained from the various concentrations readable on copending claim 1. Therefore, the ordinary skilled artisan in this field would have recognized that the instant invention is an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30 and 36-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-19, 21-24 and 31 of copending Application No. 11/407,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Copending claims are readable on an aqueous solution of silver citrate formed by electrolytically generating silver ions within a solution of citric acid (claim 16). The electrolytically generated silver citrate can form the $Ag^{+}CA^{-}$ complex (claim 18). The originally generated silver citrate can have a concentration of 1-10,000 ppm (claims 22 and 24).

Even though the copending claims do not specify the concentration of the citric acid, one having ordinary skill in the art would have been motivated to supply sufficient citric acid to complex with the generated silver and to have sufficient excess to shift the equilibrium to formation of the complex. Such amount would have been within the

instant claimed amounts. Therefore, the ordinary skilled artisan in this field would have recognized that the instant invention is an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness type double patenting ground of rejection over 10/434,742 was previously withdrawn because the claims there are now directed to a process of making (see restriction requirement history).

The obviousness type double patenting ground of rejection over 11/060,013 was previously withdrawn because the elected and examined claims there are now directed to a distinct process of treating a food product (see restriction requirement history).

The obviousness type double patenting ground of rejection over 10/846,221 was previously withdrawn because that case has been abandoned.

Grounds of rejection that are not repeated here from the previous Office action of 6/22/2007 are withdrawn upon reconsideration and in view of applicant's remarks relative thereto.

Applicant is advised that the drawings were objected to by the Draftsperson in the Office action of 6/22/2007. Applicant has failed to correct the drawings. It is so noted for the record.

Applicant is requested to update the status of all related applications, including their filing dates and patent numbers or abandoned status, if any.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616